

## REMARKS

Claims 35-54 are currently pending.

Applicant acknowledges that the rejection of Claims 35-54 under 35 U.S.C. 103(a) over Knudsen et al., US 6,458,924, has been withdrawn. Applicant also acknowledges that the applications listed on the Form 1449 received June 8, 2005 were not considered by the Examiner. Applicant herewith submits the applications previously cited in the Form 1449.

Claims 35-54 stand rejected under the judicially created doctrine of obviousness type double patenting over Claims 1-11 of US 6,358,924 in view of Knudsen et al., US 6,458,924. Claim 53 has been objected to for informalities. Claims 53-54 are rejected under 35 U.S.C. 112, second paragraph for failing to provide antecedent basis for the limitation "to patients".

Claim 53 has been amended in response to the Examiner's objection. In addition, the phrase "to patients" in Claims 53-54 has been deleted to correct the alleged insufficient antecedent basis. Applicant submits basis for the amendment can be found throughout the Specification, particularly on Page 1, line 20 through Page 2, line 9.

Applicant submits Claims 35-54 are now in a condition for allowance and respectfully request that the Examiner allow the Claims.

## REJECTIONS AND OBJECTIONS

### Rejection of Claims 35- 54 Under Obvious-type double patenting

Claims 35-54 are rejected under the judicially created doctrine of obviousness type double patenting over Claims 1-11 of US 6,358,924 (USPN '924) in view of Knudsen et al., US 6,458,924. Examiner submits

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the claimed composition of USPN '924 to substitute the anionic surfactants with a polymeric Tween surfactant because one of ordinary skill in the art, based on Knudsen's disclosure, would reasonably expect a tween surfactant to be equally effective in stabilizing the GLP-1 containing formulations. (Paper No.082105 p. 3)

Applicant submits this is an improper rejection because Knudsen et al. cannot properly be used as prior art against the Applicant. The subject matter relied upon in Knudsen et al. by

the Examiner is not entitled to the benefit of the claimed priority documents US 60/035,904 ('904 application), US 60/036,255 ('255 application), and US 60/036,226 ('226 application).

Specifically, Knudsen et al. cannot properly claim the benefit of the '904 application as it does not meet the requirements of 35 U.S.C. 119(e). In addition, the '255 and the '226 applications contain no disclosure of "tween polymeric surfactants". Further, Applicant has antedated the remaining applications to which Knudsen et al. claims benefit. As Knudsen et al. does not disclose the subject matter relied upon by the Examiner before the filing date of the present application, Knudsen et al. cannot properly be combined with USPN '924 to render the Applicant's Claims obvious.

Applicant further submits the disclosure provided by the '255 and the '226 applications in view of USPN '924 do not establish a prima facie case of obviousness. As there is no disclosure of a "tween surfactant" as asserted by the Examiner in the '255 and the '226 applications, there is no suggestion or reasonable expectation of success of using a "tween surfactant" as required for a prima facie case of obviousness.

**I. Knudsen et al. cannot be used as prior art to Applicant's Claims**

**a. Knudsen et al. cannot properly claim priority to US 60/035,904**

Applicants submit that Knudsen et al. cannot properly claim priority to the '904 application because there is no common inventor between the '904 application and Knudsen et al as required by 35 U.S.C. 119(e)(1). 35 U.S.C. 119 (e)(1) states:

(e)(1)An application for patent filed under section 111(a) . . . for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, **by an inventor or inventors named in the provisional application**, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed . . . .  
(emphasis added)

A review of US 60/035,904 indicates that the inventors are

Alan D. Wiley,  
Anthony Harriman,  
Brian Jeffreys, and

David W. Ingham

The inventors listed on Knudsen et al. are

Lisolette Bjerre Knudsen,  
Per Olaf Humsfeldt, and  
Per Franklin Nielsen.

As there are no common inventors between the '904 application and Knudsen et al., Knudsen et al., cannot properly claim priority to the '904 application under 35 U.S.C. 119(e)(1) and as such cannot be relied upon by the Examiner.

- b. Knudsen et al. priority applications US 60/036,255 and US 60/036,226 do not suggest or disclose "surfactants"

Applicant has reviewed the '255 and '226 applications and submit that there is no disclosure or suggestion of "tween polymeric surfactant" provided by the '255 and the '226 applications. The '255 and the '226 applications therefore, do not properly support the subject matter relied upon by the Examiner under 35 U.S.C. 112, first paragraph, and as such, the subject matter is not entitled to the filing dates of these applications. As Applicant has antedated the remaining applications to which Knudsen et al. claims benefit with the 37 CFR 1.131 Declaration and Exhibits filed on June 8, 2005 and June 13,2005, the subject matter relied upon by the Examiner does not have an effective filing date prior to Applicant's reduction to practice. Therefore, Knudsen et al. is not prior art to the Applicant and cannot be relied upon by the Examiner in making the rejection of obvious-type double patenting. Applicant respectfully requests the withdrawal of the rejection in view of these arguments.

**II. USPN '924 and Knudsen et al. do not establish a prima facie case of obviousness**

Applicant also submits that USPN '924 and the Knudsen et al. priority documents, the '255 and the '226 applications, do not establish a prima facie case of obviousness because there is no suggest or motivation to combine the teachings of Knudsen et al. with the teachings of USPN '924 and there is no reasonable expectation of success at arriving at the claimed invention.

The Examiner states:

USPN '924 does not claim a formulation containing a buffer and a tween polymeric surfactant. However, the Examiner refers to Knudsen et al., which disclose a stable pharmaceutical composition containing a GLP-1 derivative as well as a preservative, a buffer and a surfactant, wherein the surfactant may be a polymeric Tween surfactant or an anionic surfactant. (Paper No 082105 p.3)

As Applicant has indicated, the subject matter relied upon by the Examiner is not entitled to the filing dates of the '255 and the '226 application and as such, there is no disclosure of a surfactant prior to Applicant's reduction to practice of an embodiment of the invention. Applicant further submits that in the absence of the disclosure of surfactants in the '255 and the '226 applications, the Examiner has not established a prima facie case of obviousness. As a prima facie case of obviousness has not been established, Applicant respectfully request withdrawal of the rejection.

#### **Objection to Claim 53**

Claim 53 has been objected to because the phrase "treating a person having a condition for which administration of a GLP-1 compound to patients with elevated glucose levels" is awkwardly written. Applicants have amended Claim 53 and believe Claim 53 is now allowable.

#### **Rejection of Claims 53-54 Under 35 U.S.C. 112, Second paragraph**

Claims 53-54 have been rejected as providing insufficient antecedent basis for the limitation "to patients." Applicant has amended Claim 53, to which Claim 54 depends, to clarify that the person to be treated has a condition characterized by elevated blood glucose levels. As Claim 53, no longer recites "to patient", Applicant submits the rejection is moot and request withdrawal of the objection.

CONCLUSION

Applicant believes that the rejections and objections submitted by the Examiner have been traversed and respectfully ask that the Examiner allow all pending claims.

Respectfully submitted,



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